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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,023	10/30/2003	Ashley S. Davis		7463

7590 03/22/2006

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EXAMINER

GITOMER, RALPH J

ART UNIT PAPER NUMBER

1655

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/696,023

Applicant(s)

DAVIS ET AL.

Examiner

Ralph Gitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Applicant's election without traverse of Group I, claims 1-17, in the reply filed on 2/3/06 is acknowledged.

The specification should be reviewed to assure it is in conformance with standard US Patent Practice, for example, there is no Brief Description of the Drawings. The IDS received 10/30/03 has been considered to the extent possible. No references are found in this file and the NPL is not readily available to the examiner.

The claims are drawn to a method of preserving tissue culture cells combining two standard methods, fixation and lyophilization. Regarding the dependent claims directed to various mammalian cells, treated cells and cell preparations, it is the preservation method that is claimed and what cells are preserved is given no patentable weight. It is noted that claim 1 is directed to preserving cells and claim 3 includes a shelf life, however, for what function or to what degree the cells are preserved is not claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Ryan in view of Kortright.

Ryan (6,337,189) entitled "Fixative System, Method and Composition for Biological Testing" teaches in column 2 lines 17-21, tissue fixation to maintain cell detail. In column 2 last line, propylene glycol and methanol are fixatives. In column 7 additional compounds including polyols, various buffers, carbohydrate polymers, and ethanol are listed in the solution components.

The claims differ from Ryan in that after fixing the cells, they are then lyophilized.

Kortright (5,059,518) entitled "Stabilized Lyophilized Mammalian Cells and Method of Making Same" teaches in column 2 lines 28-46, mammalian cells are lyophilized without adversely changing the morphology of the cells and without rendering the cell membrane permeable, and stabilizing the protein structure of the cell membrane so that surface protein markers are not destroyed. Stability and shelf life of

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the lyophilized mammalian cell is retained. In column 9 lines 16-20, shelf life of the lyophilized product was in excess of 5 months under cool conditions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the standard method of fixing as taught by Ryan in combination with the standard method of lyophilizing as taught by Kortright because each method separately is known to be performed to preserve cells and to perform multiple known preservation techniques for their known function to preserve cells with the expected results would have been obvious.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

The claims must be carefully rewritten in accordance with standard US Patent Practice. They are not in method claim format.

In claim 1 line 1, what is fixed is unclear, "the cells" should be inserted after "fixing." In claim 1 and all occurrences, "using" does not state what the agent may be or for what it is used. The steps must be positively recited in gerund form. In the dependent claims, the claims must begin with a definite article. "A method as described in claim 1" is not standard claim language. In claim 2 the structure detail of what is not seen. It is unclear if claim 3 is intended to be a product by process claim and what the

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product may be is not seen. In all occurrences, how the method is suitable is not understood in context. In claim 9 which other cell lines is not set forth.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Caldwell (5,776,754) teaches cell preparation.

Baust (6,921,633) entitled "Methods and Compositions for the Preservation of Cells, Tissues or Organs in the Vitreous State" teaches in column 2 last paragraph, a vitrification composition may include sugars, carbohydrate polymers, glycols, dextrans, glycerol, starch and methanol.

Vincek (US 2003/0211452 A1) teaches preserving cells with PEG and methanol.

Hurley (EP 0 772 972 A1) teaches methanol and a buffer for preserving cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer  
Primary Examiner  
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GROUP 1200